

EXHIBIT E

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

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5 IN RE: ETHICON, INC. PELVIC :MDL NO. 2327
 REPAIR SYSTEM, PRODUCTS :
6 LIABILITY LITIGATION :VOLUME II
 :
7

8 THIS DOCUMENT RELATES TO ALL CASES AND
9 VARIOUS OTHER CROSS-NOTICED ACTIONS
10 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

11 - - -

12 January 8, 2014

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14 Transcript of the continued deposition of
15 THOMAS A. BARBOLT, Ph.D., called for Videotaped
16 Examination in the above-captioned matter, said
17 deposition taken pursuant to Superior Court Rules of
18 Practice and Procedure by and before Michelle L.
19 Gray, a Certified Court Reporter, Registered
20 Professional Reporter, and Notary Public, at the
21 offices of Riker Danzig Scherer Hyland & Perretti
22 LLP, Headquarters Plaza, One Speedwell Avenue,
23 Morristown, New Jersey, commencing at 9:07 a.m.

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1 after ten years revealed no changes in material.

2 That's not actually true, is it?

3 MR. THOMAS: Object to the form of
4 the question; scope.

5 BY MR. THORNBURGH:

6 Q. That statement that Ethicon had
7 previously implanted Prolene suture into dogs, and
8 explants after ten years revealed no changes in the
9 material, is not a true statement, is it?

10 MR. THOMAS: Object to form; scope.

11 THE WITNESS: There were three
12 elements, three important elements in that study.

13 The key elements, as we've discussed
14 earlier, were molecular weight and tensile strength.
15 And in that seven-year dog study, which -- which is
16 referenced as ten year here, there was no impact on
17 molecular weight, nor tensile strength.

18 BY MR. THORNBURGH:

19 Q. There was surface cracks observed on
20 the surface layer of the polypropylene in that
21 study, correct?

22 A. Surface changes were observed in some
23 of the fibers in some of the dogs.

24 Q. Are you telling the ladies and
25 gentlemen of the jury that when the outer surface of

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1 the polypropylene fibers crack and peel away from
2 the surface, that that is not degradation?

3 MR. THOMAS: Object to the form of
4 the question.

5 THE WITNESS: I am telling listeners
6 that the key endpoint of adverse effects of
7 degradation are molecular weight and tensile
8 strength, both quantitative measures, not subjective
9 assessments of surface changes, but quantitative
10 measures that hold great weight and suggest that
11 there's no degradation to the Prolene fiber in terms
12 that are significant.

13 BY MR. THORNBURGH:

14 Q. Do you agree there's been studies
15 conducted that show that when the polypropylene
16 fiber surface or lose -- or fragments come off of
17 the polypropylene surface as a result of
18 degradation, that that increases the inflammatory
19 response?

20 MR. THOMAS: Object to the form of
21 the question.

22 BY MR. THORNBURGH:

23 Q. You've seen those studies, haven't
24 you?

25 MR. THOMAS: Object to the form of

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1 MR. THOMAS: Object to the form of
2 the question; scope.

3 THE WITNESS: 2007?

4 BY MR. THORNBURGH:

5 Q. I'm sorry. October 29, 1997.
6 Correct?

7 A. Okay. That would be the time of the
8 submission of the 510(k) for TVT original or
9 retropubic.

10 Q. Right. So October 29, 1997 Ethicon
11 submitted to the FDA the 510(k) submission related
12 to the TVT-Retropubic, correct?

13 A. Yes.

14 Q. And in that submission, Ethicon
15 stated that the material is not absorbed, nor is it
16 subject to degradation.

17 Do you see that?

18 A. Yes.

19 Q. But as we've already established, by
20 1990 and 1992, Ethicon was aware from its own
21 internal studies that the Prolene in the TVT was
22 subject to surface degradation, correct?

23 MR. THOMAS: Object to the form of
24 the question.

25 THE WITNESS: We've talked a lot

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1 about this before.

2 BY MR. THORNBURGH:

3 Q. Correct?

4 A. And as I indicated before, there were
5 three endpoints in that experiment that are
6 important: Subjective observations, observations by
7 a human being about what's on the surface of the
8 suture, and then quantitative assessments of
9 molecular weight, and quantitative assessments of
10 tensile strength.

11 In terms of surface changes, surface
12 changes were reported. In terms of molecular weight
13 and tensile strength, no impact on either of those
14 parameters, which would lead one to conclude that
15 there's no evidence of degradation that's
16 meaningful.

17 MR. THORNBURGH: Move to strike;
18 nonresponsive.

19 BY MR. THORNBURGH:

20 Q. Sir, do you think it's okay for
21 Ethicon to misrepresent information in a 510(k)
22 submission to the FDA regarding surface cracking?

23 MR. THOMAS: Object to the form of
24 the question.

25 THE WITNESS: I don't think they've

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CERTIFICATE

I HEREBY CERTIFY that the witness was
duly sworn by me and that the deposition is a true
record of the testimony given by the witness.

It was requested before completion of
the deposition that the witness, THOMAS A. BARBOLT,
Ph.D., have the opportunity to read and sign the
deposition transcript.

MICHELLE L. GRAY, a Registered
Professional Reporter, Certified
Shorthand Reporter and Notary Public
Dated: January 16, 2014

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and/or supervision of the certifying reporter.)